U.S. Environmental Protection Agency
Office of Pesticide Programs
October 11, 2006

Guidance for Supporting the Inert Ingredients Subject to the Revocation Notice of August 9, 2006

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This document provides guidance for parties interested in supporting inert ingredients that were revoked because of insufficient data. In the final rule published in the Federal Register on Wednesday, August 9, 2006 (71 FR 45415), a number of inert ingredient tolerance exemptions were revoked because insufficient data were available to EPA's Office of Pesticide Program's (OPP) to make the safety finding required by Food Quality Protection Act (FQPA). The Inert Ingredient Assessment Branch (IIAB), which is in OPP's Registration Division (RD), has developed this guidance document to provide suggestions on how interested parties can support inert ingredients that were revoked in the final rule. It is important to note that the process and steps described in this guidance document are not mandatory, rather, they are provided as suggestions that may help the supporting parties and IIAB work together efficiently.

The revocation of these tolerance exemptions is effective on August 9, 2008, thus providing two years for the submission of supporting data to EPA and Agency decision-making. This document pertains only to the tolerance exemptions that are included in the August 9th final rule.

1. Consultation with EPA is recommended.

A party (or parties) interested in supporting an inert ingredient tolerance exemption, or a chemical that is part of a tolerance exemption, is encouraged to first request a conference with IIAB prior to embarking on testing. The IIAB believes this consultation, which can be a meeting or conference call, will save time and resources for both IIAB and the party interested in supporting the inert ingredient. The following will be discussed during a consultation:

a. Available data. IIAB will identify the data on the inert ingredient that were available to the Agency during the FQPA reassessment. The data gap(s) will then be identified as well as the type of study or studies needed to fill the data gap(s). The IIAB expects that for the majority of the inert ingredients a study such as OPPTS' Harmonized Test Guideline 870.3650 (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, which is similar to OECD's 422 study) would fulfill the data gaps and allow IIAB to make a reassessment determination. In turn, the supporting party can identify any additional data that are available to them.
b. Determination of chemical(s) to be tested. For tolerance exemption expressions that include a range of chemicals, it is quite possible that representative chemicals can be identified for testing rather than needing to test every chemical covered in the exemption, therein reducing the total the total number of studies that are conducted as well as the total cost of testing.
c. Information helpful for consultations:

- The Chemical Abstracts Service (CAS) Name and Registry Number of the specific chemical or chemicals to be supported.
- The TSCA inventory status of the chemical or chemicals.
- If available, provide summaries of valid, scientifically sound studies that already have been completed on the chemical and the source of the existing study, i.e. company files, published literature. If the party wants to submit a study that was conducted on a chemical other than the exact inert ingredient being supported, a structural activity relationship rationale must be provided to IIAB that adequately describes why the tested chemical is a suitable analog for the inert ingredient.
- If a range of chemicals are being supported (e.g., a range chain lengths; $C_8 - C_{70}$), a full description of the chemicals that have existing data, and/or which ones would be proposed for studies along with a full rationale for the test substance selection(s).
- Approximate timing of submission of existing data i.e., the full studies, and the generation and submission of additional studies.

2. <u>Demonstration of Support</u>.

After consultation with the Agency, parties who want to support an inert ingredient should communicate the following information to IIAB by August 1, 2007. Submission of the following information by August 1, 2007 will help EPA plan for data reviews and help ensure the continuance of the chemical's tolerance exemption without interruption.

a. Which tolerance exemption(s) you are supporting (as described in the CFR). If you are not supporting all the chemicals covered in a tolerance exemption, identify the chemical(s) you are supporting and the tolerance exemption expression under which the chemical(s) fall. If existing valid, scientifically sound studies that already have been completed will be submitted to fill the data gap, identify the type of study (e.g., oral developmental), the guideline number if available, and an estimated timeline for submission.
b. If no existing data are available that fills the data gap, identify the test(s) to be conducted, the guideline number(s), and the chemical(s) to be tested.
c. If testing is to be conducted, provide evidence that you have contracted with a laboratory to conduct the study(s) and include the 1) name, address, phone number, and contact person of the laboratory, 2) the estimated date when the test will be initiated, and 3) the estimated date when the test will be completed.

The above information can be communicated to IIAB in one letter or email (the last section of this guidance provides addresses) or in multiple letters and/or emails as the information becomes available as long as all of it is submitted by August 1, 2007.

Parties should inform IIAB (via letter or email) when a study is completed and provide an approximate date of when it will be submitted to IIAB. This will allow IIAB to schedule a timely review.

The Agency recommends that parties notify IIAB quickly (via letter or email) when unforeseen or other circumstances arise that will make it challenging to complete the data development work within the 2-year revocation timeframe. Examples of such problems include: no laboratories are available to conduct the study in a timely manner, or if preliminary results from the study indicate issues of concern. IIAB will work with supporters of inert ingredients on

a case by case basis when serious, unforeseen problems arise. IIAB will consider extending the expiration date of individual inert ingredient tolerance exemptions on a case-by-case basis when legitimate, extenuating circumstances become known. IIAB may be able to, through rulemaking, delay the effective date of the revocation to allow sufficient time for testing and data submission to be completed if the supporter of the inert ingredient informs IIAB of challenging circumstances as they arise, and, most importantly, provides IIAB with early indications of data that would support a safety finding.

It is important to note that IIAB will not release the identity of supporting parties or any other information provided in the letters/emails except for the identity of the inert ingredient and specific tolerance exemption being supported. The reason IIAB will not consider the identity of the inert ingredient as Confidential Business Information (CBI) is because the Agency would like to be able to share with stakeholders which inert ingredients are being supported and conversely, which are **not** being supported. If you wish to include other information that is CBI, please follow the Agency's guidance for mailing CBI and mail your letter to the IIAB at the addresses given below. The Agency recommends for security purposes that parties not fax or e-mail any document or correspondence containing CBI.

3. Evaluation of Data.

For all studies submitted for review (existing or new), IIAB will send to the submitting party a timeline for the study's review. IIAB will evaluate the studies in a timely manner and respond back to the submitter with the results of the evaluation. Studies will be reviewed in the order in which they are received. Review times will vary depending upon the complexity of the data; however, EPA does not expect that review times will hinder the reassessment effort. Turn-around times for the review of data packages for individual chemicals are anticipated to be 2-4 months depending upon the complexity of the studies. If all studies for a specific chemical or chemical group are submitted together, they will remain in the queue together. If they are submitted separately, they will be reviewed as such and combined to craft the decision document.

IIAB requests that existing studies be submitted as soon as possible to ensure the timely review and decision about whether the study will satisfy the datagap. IIAB will immediately inform the study's submitter if the study(s) is deficient and discuss whether the generation of new data may support the making of the FQPA safety finding or if additional studies are needed as confirmatory data. No additional studies will be suggested if test results show significant risks of concern.

4. Decision document.

IIAB will develop a decision document upon completion of the review of the data submitted for a chemical or group of chemicals. IIAB will transmit the final decision document to the supporting party(s). If the final decision is that the data for the chemical(s) do support the FQPA safety finding, a Notice in the Federal Register will be published that either:

a. reinstates the tolerance exemption currently under revocation (reinstatement of the exemption is only possible when all chemicals in the tolerance exemption expression are included and supported in the decision document), or

b. establishes a new tolerance exemption for the chemical or chemical group that is being supported (the process for establishing a new tolerance exemption requires that a proposed rule with a 60-day public comment period and a final rule be published in the Federal Register).

Contact Information

The following people should be contacted to:

- arrange for a consultation,
- submit a letter expressing your intention to support an inert ingredient,
- report interim process steps,
- alert IIAB when serious, unforeseen problems arise,
- ask technical questions, such as questions about chemical nomenclatures and chemicals included in inert ingredient tolerance exemptions.

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Kerry Leifer, Team Leader
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For general information on the final revocation rule, please contact:

Karen Angulo, Team Leader
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703-306-0404

The Agency recommends for security purposes that parties not fax or e-mail any document or correspondence containing CBI.

Mailing documents and correspondence

Hardcopies of letters and documents can be mailed to the Inert Ingredient Assessment Branch at the addresses below:

Mail

Document Processing Desk (Inert Ingredient Assessment Branch - IIAB)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Courier Address:
Inert Ingredient Assessment Branch (IIAB)
Office of Pesticide Programs
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202